

REMARKS / ARGUMENTS

This amendment is submitted in full response to the outstanding Office Action dated January 20, 2010, wherein Claims 2, 4, 9 and 12 stand rejected under 35 USC 103(a) as being unpatentable over Turner et al (U.S. Patent No. 4,817,603) in view of Czernecki et al. (U.S. Patent No. 5,356,420).

For the reasons set forth in greater detail hereinafter, and in light of the newly submitted claims accompanying this amendment, the outstanding rejections are respectfully traversed.

APPLICANT'S INVENTION

As now defined in newly submitted independent Claim 14 and dependent Claim 15, the Applicant's invention is directed to a lancet device comprising a housing, a lancet moveably disposed within the open interior of the housing and including a piercing tip. Further, a biasing assembly is disposed within said housing in direct interconnected relation between the housing and the lancet and being separated from and independent of an engagement assembly. A cocking seat is detached from the lancet and movable relative to the housing in driving relation to said lancet.

In addition, an engagement assembly is disposed on the lancet and movable with and relative to the lancet. Moreover, the engagement assembly comprises an engagement member now specifically defined as including a single use, breakable hinge movably connected to a remainder of said lancet. Further, said breakable hinge releasably interconnects the remainder of said lancet to the cocking seat. A release element is fixedly secured to the housing and movable therewith into releasing engagement with the breakable hinge.

The breakable hinge is more specifically defined as including a reduced thickness section structured to break upon deforming engagement with the release element and disengage the remainder of said lancet from engagement with the cocking seat. As a result of the recited structural and operative features of the above noted components of Applicant's lancet device, the biasing assembly is disposed into direct biasing engagement with the lancet and the piercing tip and is independent of the release element. As a result, disengagement between the lancet and the cocking seat causes a firing of the lancet and piercing tip.

Newly submitted dependent Claim 15 even more specifically defines Applicant's invention as including a retention member

releasably engaging and being detached from the breakable hinge. The retention member is disposed in driving relation to the lancet via the breakable hinge.

REFERENCE OF RECORD - ISSUES UNDER 35 USC 103

A thorough review of Turner et al., considered either singularly or in combination with Czernecki et al, indicates that Applicant's specifically claimed invention includes components which are both structurally and operatively cooperative and define the workings of Applicant's lancet assembly. More specifically, as applied by the Examiner, the Turner et al. reference discloses a cocking seat 68, a housing 82, a lancet 34 and an engagement member 18, 90 secured to the lancet 34. The Examiner further interprets the Turner et al. reference as including a retention member 74 disposable into engaging relation with the engagement member 18, 90.

The Examiner has recognized that Turner et al. does not disclose Applicant's engagement member as comprising a single use breakable hinge moveably connected to a remainder of said lancet and releasably interconnecting the remainder of said lancet to the cocking seat. In order to overcome this recognized deficiency of Turner et al., Czernecki et al is

relied on as teaching the use of a breakable engagement member(s) 11 that break to prevent reuse of a lancet device.

First with regard to Turner, et al, Applicant contends that this reference is deficient for the following reasons:

Turner et al. does not disclose the biasing assembly which is independent of a release element and which is disposed in direct, interconnecting relation between the housing and the lancet. In contrast, Turner et al discloses a biasing assembly 16 disposed in interconnecting relation between the housing and what Applicant refers to as the release member 88. As such, the biasing member 16 of Turner et al is directly connected to the release element and is not disposed in direct interconnection between the housing and the lancet, independently of the release element.

Turner et al, does not disclose a release element fixedly secured to the housing and movable therewith into a a deforming engagement with a breakable hinge, wherein the breakable hinge defines the engagement member of the engagement assembly. In contrast, Turner et al is completely absent the teaching of the single use, breakable hinge to define the engagement member. Instead, Turner et

al includes the engagement member 18, 90 being a fixed part of the lancet 34 and being fixedly secured, at least initially, to the cocking seat 68 by virtue of the retention member 74.

Turner et al. fails to disclose the breakable hinge including a reduced thickness section structured to break upon deforming engagement with the release element and thereby disengage said remainder of said lancet from engagement with the cocking seat. In contrast, the engagement member 18, 90 of Turner et al, being initially fixed to the cocking seat 68 is released there from when movably connected and biased release member 83 comes into engagement therewith as demonstrated in Figure 6A through 6C of the Turner et al reference.

As set forth above, the examiner relies on Czernecki et al. as disclosing or at least rendering obvious Applicant's engagement member comprising a single use, breakable hinge. However, a thorough review of the Czernecki et al reference discloses a pre-cocked lancet device retained in the pre-cocked position by a pair of wings 11.

As a result, Czernecki et al is absent the following operative and structural features:

Czernecki et al is absent an engagement member including a single use, breakable hinge which is movably connected to a remainder of the lancet and wherein said breakable hinge releasably interconnects the remainder of the lancet to a cocking seat.

Czernecki et al is absent any disclosure or suggestion of a "cocking seat" as now defined in Applicant's invention, in that the device is pre-cocked.

Czernecki et al does not disclose a breakable hinge including a reduced thickness section structured to break upon deforming engagement with the release element.

Czernecki et al does not disclose a release element fixedly secured to the housing and movable therewith into deforming engagement with a breakable hinge.

Based on the above deficiencies in the disclosures of both Turner et al and Czernecki et al, Applicant contends that the Turner et al reference would be inoperable in its intended manner if it were to include a single use, breakable hinge removably connected to the lancet, wherein the breakable hinge releasably interconnects the remainder of the lancet to the cocking seat. Further, neither Turner et al nor Czernecki et al disclose a breakable hinge defined by a reduced thickness

section structured to break upon deforming engagement with the release element, so as to disengage the remainder of the lancet from engagement with the cocking seat.

Conclusion

Accordingly, Applicant's invention is more specifically defined and the Examiner is respectfully requested to reconsider his position in light of newly submitted Claims 14 and 15 which are believed to describe Applicant's invention in a manner which clearly overcomes the references of record, as applied by the Examiner.

Based on the above amendments and remarks it is believed that this application is now in condition for allowance and such action is respectfully requested.

In addition, a request for an appropriate extension of time is enclosed herewith along with the corresponding PTO fee. In the event that any additional fee may be required by the filing of this paper, the Commissioner is hereby authorized to charge any fees and/or credits to our **Deposit Account No. 13-1227**.

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Respectfully Submitted,

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